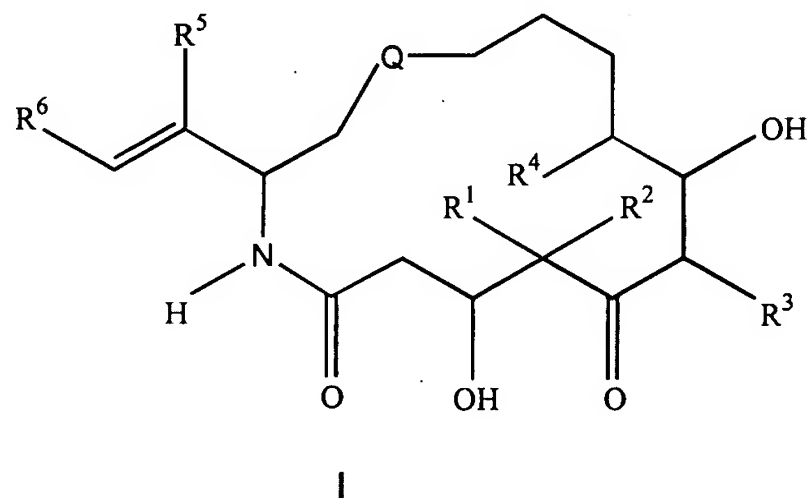


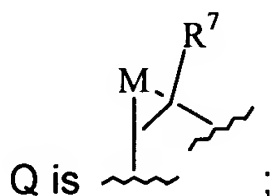
IN THE CLAIMS:

The following is a complete listing of all claims upon entry of this Amendment:

- 1 (Currently amended). A process for formulating, ~~for parenteral administration~~, an epothilone analog represented by formula I:



and/or a pharmaceutically-acceptable salt, geometric, optical, or stereoisomer thereof,
wherein:



M is oxygen;

each R¹, R², R³, R⁴, R⁵, and R⁷ is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein R¹ and R² are alkyl, they can be joined to form cycloalkyl;

R⁶ is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, and heterocyclo;

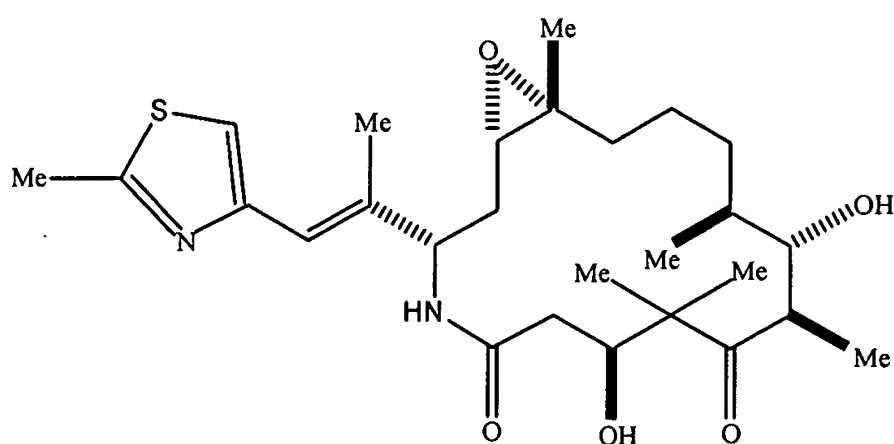
and any salts, solvates, or hydrates thereof, comprising the following steps:

a) dissolving said epothilone analog in a mixture of at least about 50% by volume tertiary-butanol in water to form a solution;

b) performing primary drying of said solution at a temperature of from about -10°C to about -40°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours to form a primary lyophilized product; and

c) performing secondary drying of the primary lyophilized product at a temperature of from about 10 °C to about 30°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours to provide a lyophilized product of the epothilone analog.

2 (Currently amended). The process of claim 1 wherein said epothilone analog is represented by formula II:



II

, and/or a

pharmaceutically-acceptable salt, geometric, optical, or stereoisomer thereof.

3 (Previously presented). The process of claim 1 wherein step a) comprises first, wetting said epothilone analog with a mixture of at least about 60% tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains from about 2 mg/mL to about 30 mg/mL of said epothilone analog in a mixture of from about 50% to about 80% by volume tertiary-butanol in water.

4 (Previously presented). The process of claim 2 wherein step a) comprises first, wetting said epothilone analog with a mixture of at least about 60% tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains from about 2 mg/mL to about 30 mg/mL of said epothilone analog in a mixture of from about 50% to about 80% by volume tertiary-butanol in water.

5 (Previously presented). The process of claim 3 wherein in step a) said epothilone analog is initially wetted with a mixture of from about 60% to about 95% by volume tertiary-butanol in water.

6 (Previously presented). The process of claim 4 wherein in step a) said epothilone analog is initially wetted with a mixture of from about 60% to about 95% by volume tertiary-butanol in water.

7 (Canceled).

8 (Previously presented). The process of claim 2 wherein said primary drying in step b) is carried out at a temperature of from about -25°C to -40°C and a pressure of from about 200 to 300 millitorr.

9 (Canceled).

10 (Previously presented). The process of claim 2 wherein said secondary drying in step c) is carried out at a temperature of from about 25°C to 30°C and a pressure of from about 150 to 300 millitorr.

11 (Previously presented). The process of claim 30 wherein said surfactant is polyethoxylated castor oil.

12 (Previously presented). The process of claim 32 wherein said surfactant is polyethoxylated castor oil.

13 (Previously presented). The process of claim 30 wherein said second vial contains an amount of said mixture sufficient to form a solution of from about 2 mg/mL to about 4 mg/mL of said epothilone analog therein.

14 (Canceled).

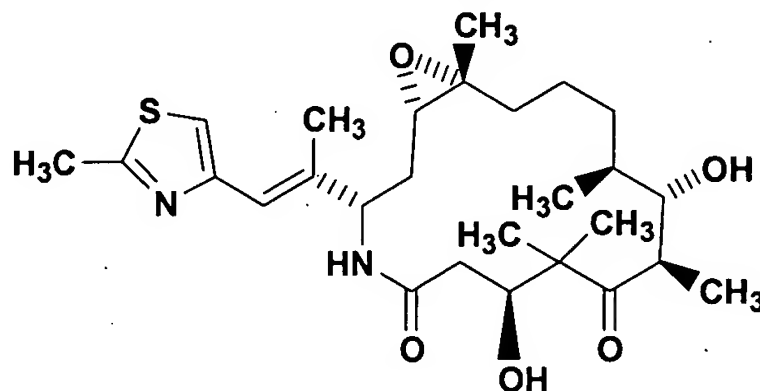
15-29 (Canceled).

30 (Previously presented). The process of claim 1, further comprising the step of:

d) packaging said lyophilized product of the epothilone analog in a first vial and packaging in a second vial a sufficient quantity of a mixture comprising at least one suitable nonionic surfactant and at least one dehydrated alcohol to effect reconstitution of the lyophilized product.

31 (Previously presented). The process of claim 30 wherein the mixture comprises about equal parts by volume of anhydrous ethanol and the at least one nonionic surfactant.

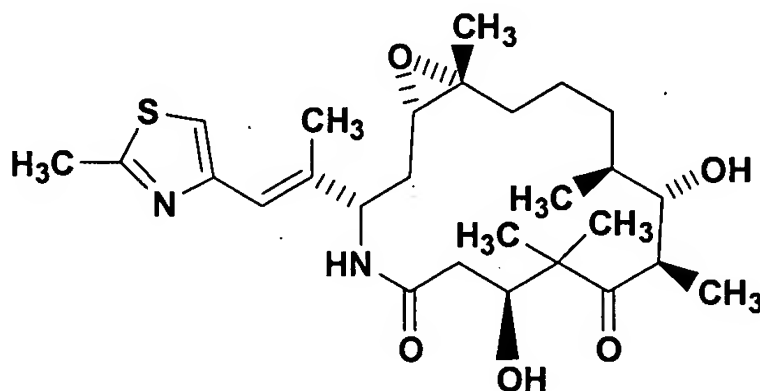
32 (Currently amended). The process of claim 30 wherein said epothilone analog is:



and/or a pharmaceutically-acceptable salt, geometric, optical, or stereoisomer thereof.

33 (Canceled).

34 (Currently amended). A process for formulating, ~~for parenteral administration,~~ an epothilone analog having the formula:



and/or a pharmaceutically-acceptable salt, geometric, optical, or stereoisomer thereof.

comprising:

- a) dissolving said epothilone analog in a mixture of tertiary butanol and water to form a solution, wherein the mixture comprises at least about 50% by volume tertiary butanol;
- b) performing primary drying of said solution at a temperature, chamber pressure and period of time sufficient to form a primary lyophilized product; and
- c) performing secondary drying of the primary lyophilized product at a temperature, chamber pressure and for a period of time sufficient to form a lyophilized product of the epothilone analog.

35 (Previously presented) The process of claim 34, wherein said step a) of dissolving said epothilone analog is carried out at a temperature below ambient temperature.

36 (Previously presented). The process of claim 34, wherein said step a) of dissolving said epothilone analog comprises first, wetting said epothilone analog with a mixture of at least about 60% by volume tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains at least about 50% by volume tertiary-butanol in water.

37 (Currently amended). The process of claim 34, wherein said step a) of dissolving said epothilone analog is carried out in the absence of an excipient.

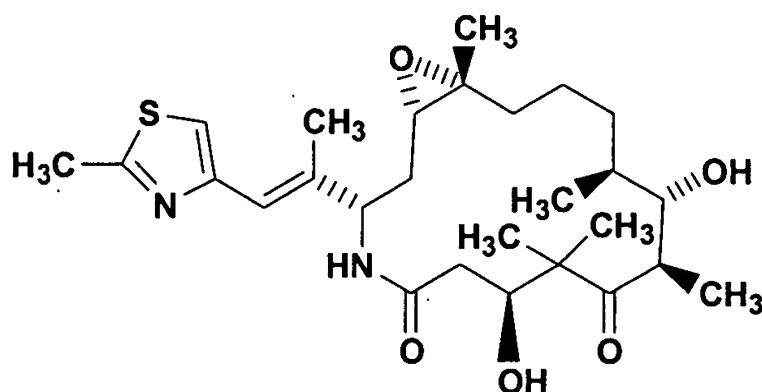
38 (Previously presented). The process of claim 34 wherein said primary drying in step b) is carried out at a temperature of from about -10°C to -40°C and at a chamber pressure of from about 50 to 300 millitorr for a period of up to about 96 hours.

39 (Previously presented). The process of claim 38 wherein said secondary drying in step c) is carried out at a temperature of from about 10°C to 30°C and at a chamber pressure of from about 150 to 300 millitorr for a period of up to about 96 hours.

40 (Previously presented). The process of claim 34, further comprising the step of:

d) packaging said lyophilized product of the epothilone analog in a first vial and packaging in a second vial a sufficient quantity of a solvent mixture to effect reconstitution of the epothilone analog, wherein the solvent mixture of the second vial comprises at least one suitable nonionic surfactant and at least one anhydrous alcohol.

41 (Previously presented). A process for formulating, ~~for parenteral administration, an~~
epothilone analog represented by formula II:



and/or a pharmaceutically-acceptable salt, geometric, optical, or stereoisomer thereof,
comprising:

a) dissolving said epothilone analog to form a solution, comprising first, wetting said epothilone analog with a mixture of at least about 60% by volume tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains at least about 50% by volume tertiary-butanol in water, wherein said step of dissolving is carried out at a temperature below ambient temperature;

b) performing primary drying of said solution at a temperature, chamber pressure and for a period of time sufficient to form a primary lyophilized product; and

c) performing secondary drying of the primary lyophilized product at temperature, chamber pressure and for a period of time sufficient to form a lyophilized product of the epothilone analog.

42 (Previously presented). The process of claim 41 wherein,

step b) of primary drying of said solution is performed at a temperature of about -10°C to about -40°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours; and

step c) of secondary drying is performed at a temperature of from about 10°C to about 30°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours to provide a lyophilized product of the epothilone analog.

43 (Previously presented). The process of claim 42 wherein,

step a) of dissolving said epothilone analog is carried out at a temperature of from about -5°C to about 15°C.

44 (Previously presented). The process of claim 43 wherein,

step a) of dissolving said epothilone analog is carried out in the absence of an excipient.

45 (Previously presented). The process of claim 43, further comprising the step of:

d) packaging said lyophilized product of the epothilone analog in a first vial and packaging in a second vial a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog, wherein the solution of the second vial comprises about equal amounts of at least one suitable nonionic surfactant and at least one anhydrous alcohol.

46 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 1.

47 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 2.

48 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 34.

49 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 39.

50 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 43.

51 (Previously presented) A pharmaceutical product comprising at least a first and a second vial wherein the first vial contains a lyophilized epothilone analog prepared according to claim 2, and the second vial contains a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog, wherein the solution of the second vial comprises about equal amounts of at least one suitable nonionic surfactant and at least one anhydrous alcohol.

52 (Currently amended) A method of treating a patient comprising, mixing the contents of the first and second vials of the pharmaceutical product of claim 51 to provide an epothilone analog solution, diluting the epothilone analog solution with a quantity of a suitable parenteral diluent to prepare an intravenous formulation, and administering the intravenous formulation to the patient.

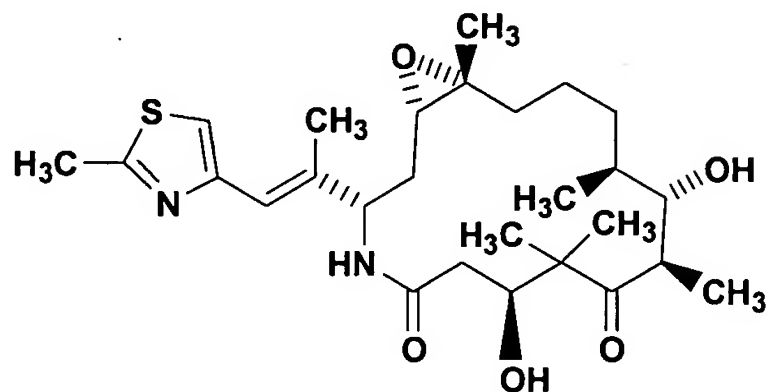
53 (Previously presented) A pharmaceutical product comprising at least a first and a second vial wherein the first vial contains a lyophilized epothilone analog prepared according to claim 34, and the second vial contains a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog, wherein the solution of the second vial comprises about equal amounts of at least one suitable nonionic surfactant and at least one anhydrous alcohol.

54 (Previously presented) A method of treating a patient comprising, mixing the contents of the first and second vials of the pharmaceutical product of claim 53 to provide an epothilone solution, diluting the epothilone solution with a quantity of a suitable parenteral diluent to prepare an intravenous formulation, and administering the intravenous formulation to the patient.

55 (Previously presented) The process of claim 34, wherein said step a) of dissolving said epothilone analog is carried out at a temperature in the range of from about 5°C to about 15°C.

56-58 (Canceled).

59 (New). A process for lyophilizing an epothilone analog comprising dissolving an epothilone analog having the formula,



and/or a pharmaceutically-acceptable salt, geometric, optical, or stereoisomer thereof, in a solvent mixture comprising tertiary-butanol and water to form an epothilone analog solution and then drying the epothilone analog solution under vacuum to provide the lyophilized epothilone analog.

60 (New). A lyophilized epothilone analog prepared according to the process of claim 59.

61 (New). A pharmaceutical product comprising at least a first and a second vial wherein the first vial contains a lyophilized epothilone analog prepared according to claim 59, and the second vial contains a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog.